

ACCU-CHEK® Inform II

Cat. No. 05871166

LINEARITY TEST KIT

For Professional Use Only

For In Vitro Diagnostic Use

Intended Use • Use only for periodic verification of linearity of the Accu-Chek Inform II system with Accu-Chek Inform II test strips and Accu-Chek Performa system with Accu-Chek Performa test strips.

Contents of the Pack • Pack containing 6 linearity solutions with varying glucose levels, linearity logs, and inserts.

Note:

- The solution can stain fabric. Wash with soap and water.
- Do not dilute solutions or combine different levels to adjust concentrations.

WARNING:

Choking hazard. Small parts. Keep away from children under the age of 3 years.

Storage and Stability • The printed use by date is valid if the unopened linearity solutions are stored at 39–86 °F (4–30 °C). The linearity solutions do not need to be kept in the refrigerator. Do not freeze.

Note:

- Write the date the bottle was opened on the bottle label. The linearity solutions are stable for 3 months from that date or until the use by date on the bottle label, whichever comes first.
- Refer to the meter Operator's Manual for system operating conditions.
- Linearity solutions taken directly from the refrigerator must be allowed to adjust to room temperature (without opening the bottle).

Procedure • Put the meter on a flat surface, such as a table. Remove the linearity solution bottle cap. Wipe the tip of the bottle with a lint-free wipe. Squeeze the bottle until a tiny drop forms at the tip. Touch the drop to the **front edge** of the yellow window of the test strip. The meter will indicate when sufficient linearity solution is in the test strip. Wipe the tip of the bottle with a lint-free wipe, then cap the bottle tightly. The result appears on the display. Record the result. Remove and discard the used test strip per facility policy. Test each linearity level twice and average the results for each level.

To avoid possible cross-contamination, do not interchange the bottle caps.

Plotting Values • Each linearity test kit consists of 6 levels of solutions manufactured to produce a linear relationship within the set. Record the following values as the target values on the x-axis of the linearity log.

LINEARITY	L1	L2	L3	L4	L5	L6
mg/dL	28	45	118	307	511	559

Expected Values • Plot the average linearity results for each of the 6 levels of linearity test kit solutions. Draw the best straight line possible through the points. Do not just connect the points. Analyze the line visually to be sure that it is the best straight line drawn through all the points regardless of the slope. The line should fall within the gray-shaded area of the graph. The upper and lower points determine the limits of the linear range. If a result falls outside of the gray-shaded area, repeat the test, calculate the average with the new linearity value, and plot accordingly. The gray-shaded area was defined based on typical system performance.

With the Accu-Chek Inform II and Accu-Chek Performa systems, a minimum of 3 readable points covering the entire linearity range may be required by the facility. A dash in either the Level 1 or Level 6 target value box indicates that the glucose result may be outside the readable range for the meter. In order to obtain the maximum linear range, include all levels which give results.

Refer to Clinical and Laboratory Standards Institute: Evaluation of the Linearity of Quantitative Analytical Methods EP6-P, Clinical and Laboratory Standards Institute, 1986, for a detailed explanation for determining linear concentration range by plotting observed responses versus standard concentration.

Presentation • Pack containing 6 x 2.5 mL linearity solutions.

Disposal • Dispose in domestic waste. Consult local ordinances as they may vary.

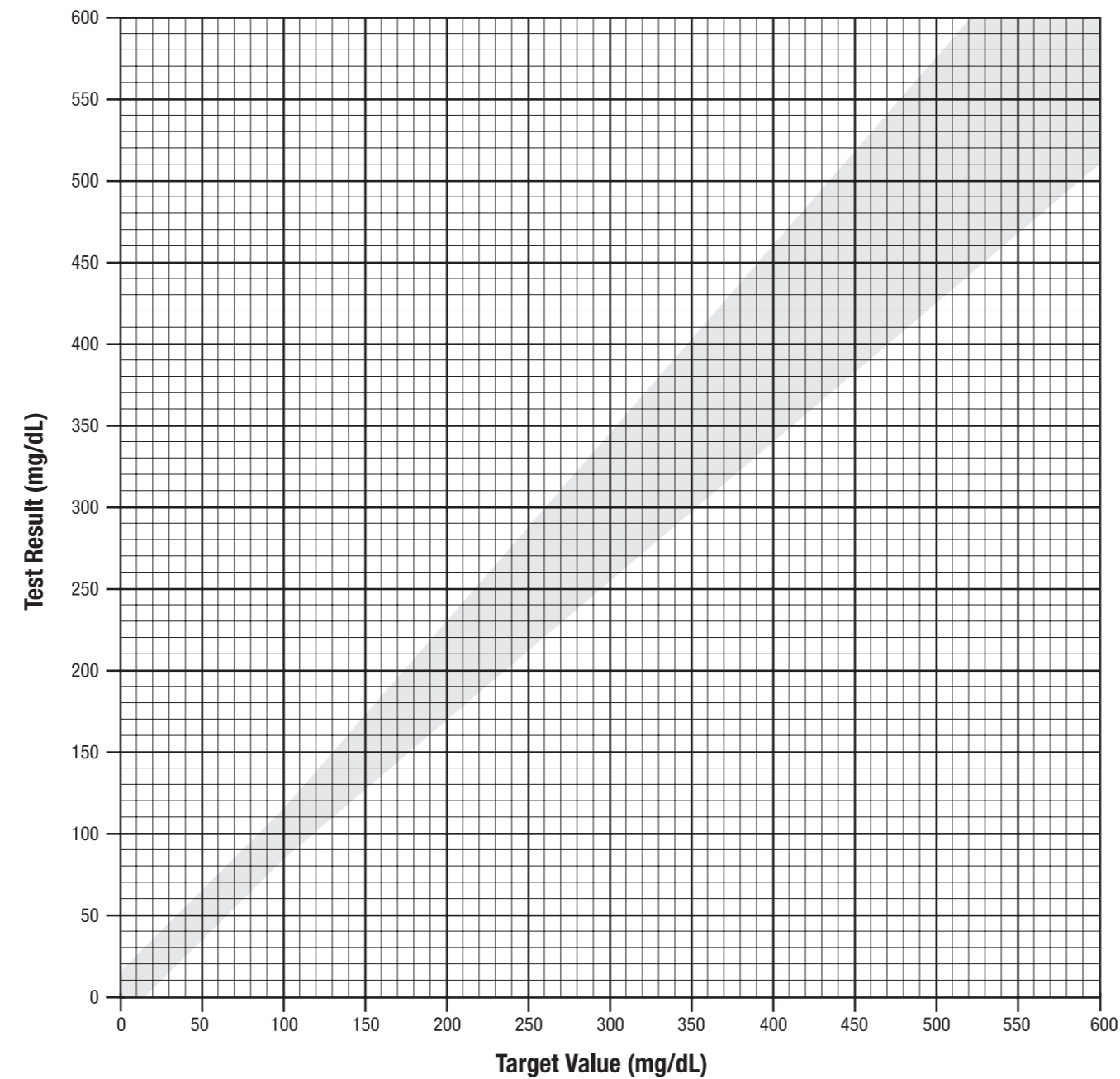
Ingredients

Component	L1	L2	L3	L4	L5	L6
Glucose	0.04 %	0.06 %	0.12 %	0.30 %	0.50 %	0.55 %
Buffer	4.84 %	4.84 %	4.84 %	4.84 %	4.84 %	4.84 %
Biological Salt	3.39 %	3.39 %	3.39 %	3.39 %	3.39 %	3.39 %
Preservative	0.30 %	0.30 %	0.30 %	0.30 %	0.30 %	0.30 %
Non-reactive ingredients	10.00 %	10.00 %	10.00 %	10.00 %	10.00 %	10.00 %
FD&C Blue #1	0.08 %	0.08 %	0.08 %	0.08 %	0.08 %	0.08 %

Percentages in weight/weight

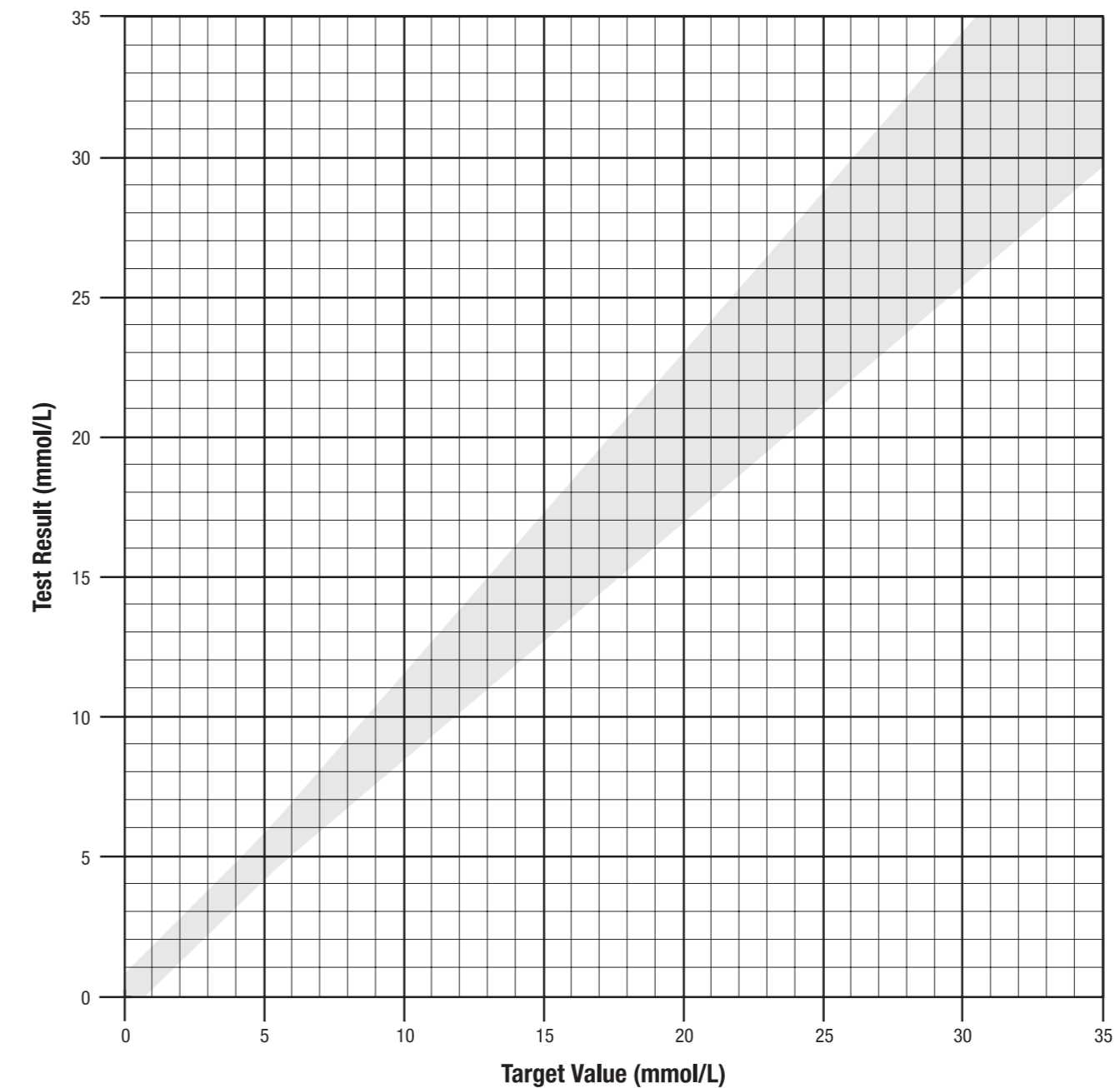
Date _____
 Test Strip Lot No. _____
 Accu-Chek System Serial No. _____
 Operator _____
 Linearity Kit Lot No. _____




Test Result (mg/dL)	1	2	3	4	5	6
1						
2						
\bar{x} (mean)						
Target Value						



Date _____
 Test Strip Lot No. _____
 Accu-Chek System Serial No. _____
 Operator _____
 Linearity Kit Lot No. _____

Test Result (mmol/L)	1	2	3	4	5	6
1						
2						
\bar{x} (mean)						
Target Value						




	Temperature limitation (store at)
	Manufacturer
	Global Trade Item Number

Roche USA – 54577
 V1/1 – 07981473001 – Black

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